

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
Richard SCHLEGEL et al)	
Serial No. 08/216,506)	Group Art Unit: 1813
Filed: March 22, 1994)	
For: PAPILLOMAVIRUS VACCINE)	Examiner: A. Caputa

DECLARATION UNDER 37 C.F.R. § 1.132 **RECEIVED**

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

MAR 24 1995

GROUP 1800

Sir:

I, John W. Kreider, declare and state that:

(1) I have been a Professor at Pennsylvania State University from 1968 to present. I have a joint appointment in the Department of Microbiology and the College of Medicine.

(2) I received a M.D. from the University of Pennsylvania in 1963.

(3) I am a well-known expert in the area of papillomavirus research. My relevant experience in this area includes the development of methods for transforming human tissues, development of papillomavirus animal models for the evaluation of potential therapeutic agents; the study of human papillomaviruses and cervical cancer; development of treatment methods for papillomavirus infections; and the immunological aspects of papillomavirus infection.

(4) I attend and give numerous lectures in the area of papillomavirus research.

(5) I am an author on numerous publications relating to papillomavirus research.

(6) I am an inventor on two United States patents relating to propagating human papillomaviruses.

(7) I am a member of the International Society for Antiviral Research.

(8) My curriculum vitae is attached as an Exhibit to this Declaration.

(9) I have reviewed the above-identified patent application by Richard Schlegel, M.D. and A. Bennett Jenson, M.D., entitled "Papillomavirus Vaccine". Based on my review thereof, it is my understanding that this application is directed to papillomavirus vaccines which contain recombinant, conformationally correct papillomavirus L1 major capsid proteins. It is my further understanding that this application is directed to human papillomavirus vaccines which contain recombinant, conformationally correct human papillomavirus L1 proteins.

(10) I have also reviewed the "Declaration Pursuant to 37 C.F.R. § 1.132" by Richard Schlegel, M.D., Ph.D., submitted on June 13, 1994, in connection with the above-identified application.

(11) It is my understanding that the Examiner assigned this application recently issued an Office Action which asserted that the above-identified application and the Schlegel Declaration are insufficient to convince one skilled in the art that recombinant, conformationally correct human papillomavirus (HPV) L1 capsid proteins may be used as an effective vaccine

for affording protection in humans against human papillomavirus infection.

(12) I disagree with the Examiner's conclusions. It is my expert opinion that the above-identified application and the Schlegel Declaration contain sufficient evidence that recombinant, conformationally HPV L1 proteins may be used as vaccines for protecting humans against papillomavirus infection. I base my opinion on at least the following.

(13) Given my established expertise in evaluating papillomavirus animal models it is my expert opinion that the COPV dog model is an adequate animal model for study of human papillomavirus infection and potential therapeutics. In fact, in my expert opinion this animal model is the best known animal model for the study of human papillomavirus infection and potential HPV vaccines. As discussed in the Schlegel Declaration, and as well known in the papillomavirus art, COPV and HPV's which cause cancer possess numerous similarities. For example, these viruses exhibit similar genetic organization, viral structure, L1 capsid protein sequences, and selectively infect a mucosal site of infection. Therefore, based on these significant similarities, it is my expert opinion that the COPV animal model is a valid animal model for predicting the efficacy of HPV vaccines.

(14) It is further my expert opinion that the Schlegel Declaration contains data which convincingly establishes that the administration of recombinant, conformationally correct papillomavirus proteins confer protection in humans against the homologous PV (wherein homologous PV refers to a papillomavirus

which expresses the same recombinant L1 protein which is administered). I base my opinion in part in the fact that the Declaration indicates that all of the 25 dogs which were inoculated with recombinant COPV L1 protein were protected, i.e., these dogs did not develop perceptible COPV infection upon challenge. By contrast, all of the control dogs which did not receive the L1 protein developed COPV infection.

(15) The Schlegel Declaration further demonstrates that serum obtained from dogs vaccinated with recombinant, conformationally correct COPV L1 protein, upon passive transfer to naive dogs confers protection. This is highly significant because this provides evidence that a protective humoral immune response to the L1 protein is obtained after administering the recombinant, conformationally correct L1 proteins.

(16) The Schlegel Declaration further contains persuasive evidence that recombinant, conformationally correct PV L1 proteins confer protection, whereas denatured papillomavirus proteins do not confer protection. Thus, the Schlegel Declaration contains evidence that proper L1 protein conformation is necessary for an adequate, i.e., protective immune response.

(17) I can further attest to the fact that the data contained in the Schlegel Declaration has been presented at several scientific meetings. Also, I have reviewed the abstracts and a manuscript derived from those presentations. The data of Dr. Jenson and Dr. Schlegel has been extremely well received and is widely regarded to provide the first convincing *in vivo* demonstration that it should be possible to administer

conformationally correct HPV proteins to human subjects in order to provide immunity against HPV infection.

(18) I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

3/1/95



John W. Kreider

Recent Extramural Lectureships (cont'd)

5/20/90	Pathology Review Course, Osler Institute, Washington, DC	Faculty Lecturer: "Neoplasia"
11/20/90	Wellcome Research Labs Burroughs Wellcome Company Research Triangle Park North Carolina	Invited Speaker: "Model Systems of Human Papilloma- virus Biology, Immunology, and Therapy"
1/15/91	Roswell Park Memorial Institute, Buffalo, New York	Invited Speaker: "Human Papillomaviruses and Cervical Cancer"
4/1/91	Collaborative Antiviral Testing Group (CATG) of the Microbiol- ogy and Infectious Diseases Program of NIAID/NIH, Bethesda, MD	"Antiviral Therapy for Shope Rabbit Papilloma"
4/25/91	Continuing Education Program CPOG Career Day for High School Students The Milton S. Hershey Medical Center, Hershey, PA	Invited Speaker: "Basic Science and Pathology of Cancer"
6/15/91	Sterling Drug Company, Albany, NY	"Animal Models for Antiviral Therapy"
7/8/91	Hershey Rotary Club Hershey Country Club	"Jake Gittlen Cancer Research Institute"
7/20/91	International Papillomavirus Workshop, Seattle, WA	Chaired Session: "Mucosal Papillomaviruses"
7/30/91	Rocky Mountain Laboratory U.S.P.H.S., Hamilton, MT	"Animal Papillomaviruses"
10/7/91	Head and Neck Cancer Model Conference, Upper Aerodigestive Organ System Working Group, NCI and University of Texas MD Anderson Cancer Center, Hershey, PA	"Animal Models of Human Papillomavirus Infections"
11/12/91	Cancer Update for Teachers, Continuing Education Program, The Milton S. Hershey Medical Center, Hershey, PA	"What is Cancer?"

Recent Extramural Lectureships (cont'd)

11/13/91	Department of Biology, Colloquium Series, Millersville University, Millersville, PA	"Love, Warts and Cancer"
12/12/91	42nd Annual Meeting, American College of Veterinary Pathologists Orlando, Florida	Invited Speaker: "Papilloma Viruses in Animals and Man"
2/24/92	Department of Microbiology and Immunology, Albert Einstein College of Medicine of Yeshiva University, Bronx, New York	Invited Seminar Speaker: "Developments in Treatment and Prevention of Human Papilloma- virus Infections"
3/15/92	Binford-Dammin Society of Infectious Disease Pathologists Atlanta, Georgia	Invited Speaker: "The Development of Animal Models for Studying Human Papilloma- Induced Squamous Cell Carcinoma"
3/19/92	Wyeth-Ayerst Research Philadelphia, PA	Invited Seminar Speaker: "Model Systems for Human Papillomavirus"
4/15/92	Collaborative Antiviral Testing Group (CATG) of the Microbiol- ogy and Infectious Diseases Program of NIAID/NIH, Bethesda, MD	"Animal Models for Evaluation of Antivirals for Papillomavirus Infections"
9/10/92	International Papillomavirus Workshop, Edinburgh, Scotland	"Evaluation of the Shope Rabbit Papilloma as a Model System in the Study of Intralesional MPI 5003 for Treatment of Conodylomata Acuminata"
6/01/94	Division of Antiviral Drug Products Food and Drug Administration Bethesda, MD	Invited Seminar Speaker: "The First Workshop On Antiviral Claims for Topical Antiseptics"

Abstracts and National Meetings

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2. Kreider, J.W. and Breedis, C. Interactions of the Shope Papilloma Virus and Rabbit Skin Cells as Demonstrated by Immunofluorescence. Proc. Am. Assoc. Cancer Res. 7:#150, 1966.
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4. Breedis, C. and Kreider, J.W. The Role of the Dermis in the Neoplastic Transformation of Epidermis by Shope Papilloma Virus (SPV). Proc. Am. Assoc. Cancer Res. 9:#29, 1968.
5. Kreider, J.W. and Breedis, C. Spontaneous Regression of Shope Papilloma Virus-Induced Papillomas of Fetal Rat Skin Transplanted to the Adult Rat. Fed. Proc. 28:#2839, 1969.
6. Kreider, J.W. and Breedis, C. Histogenetic Interactions of Enzyme-Dissociated Epidermal and Dermal Cells in Monolayer Cultures. J. Invest. Dermatol. 52:#366, 1969.
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9. Kreider, J.W., Benjamin, S.A., Pruchnic, W.F. and Strimlan, C.V. Immunologic Inhibition of the Growth of Virus-Induced Rat Epidermal Papillomas. J. Invest. Dermatol. 54:#429, 1970.
10. Kreider, J.W., Benjamin, S.A., Pruchnic, W.F. and Strimlan, C.V. Shope Papilloma Virus Induced Papillomas in Immunosuppressed Rats. International Academy of Pathology, 1970.
11. Kreider, J.W. Stimulation of DNA Synthesis of Rat Salivary Gland Cells in Monolayer Cultures by Isoproterenol (IPR). In Vitro 6:#239, 1970.
12. Jones, R.E., Kreider, J.W. and Criley, B.B. Incubation Patch of the Chicken: Response to Hormones In Situ and Transplanted to a Dorsal Site. Pacific Conference in Comparative Endocrinology, University of California, Santa Barbara, California, May 9, 1970.
13. Kreider, J.W. and Cecalupo, A. Response of Rat GVHR to Poly I-Poly C. Proc. Am. Assoc. Cancer Res. 12:#228, 1971.
14. Kreider, J.W., Haft, H.M. and Roode, P.B. Growth of Human Skin on the Hamster. J. Invest. Dermatol. 56:247-248, 1971.
15. Neely, J.E., Combs, J.W. and Kreider, J.W. A Novel Technique for Uniform Autoradiography of a Dispersed Cell Population. Fed. Proc. 30:#1145, 1971.

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17. Kreider, J.W. and Cecalupo, A.J. Poly I-Poly C (PIC) Effects on Newborn Rats. Bact. Proc. #M65, 1972.
18. Kreider, J.W., Matheson, D.W., Rosenthal, M., Beltz, B.A. and Neely, J.E. Inhibition of Melanogenesis with BUdR Treatment in a Single Cycle of DNA Synthesis. Fed. Proc. 31:#2219, 1972.
19. Kreider, J.W. and Benjamin, S.A. Tumor-Specific Immunity and Poly I- Poly C. Proc. Am. Assoc. Cancer Res. 13:#203, 1972.
20. Kreider, J.W., Wade, D.R., Rosenthal, M. and Densley, T. Modification Via the Cyclic AMP Mechanism of the Proliferation and Differentiation of B16 Melanoma Cells. Miami Winter Symposia Series: Cyclic Nucleotides in Carcinogenesis, 1973.
21. Rosenthal, M.H., Shiman, R. and Kreider, J.W. A Quantitative Fluorimetric Assay for Melanin. Fed. Proc. 32:#3647, 1973.
22. Kreider, J.W. and Combs, J.W. Immunologic Inhibition of Cellular Proliferation in Tumor Allografts. Proc. Am. Assoc. Cancer Res. 14:#198, 1973.
23. Satoh, C., Kreider, J.W. and Davidson, E.A. Complex Saacharides of Cultures Melanoma Cells Fed. Proc. 32:#2604, 1973.
24. Kreider, J.W. and Beltz, B. Spontaneous Regression of the Shope Papilloma: Relationship of Leucocytic Infiltration and Tumor Cell Proliferation. Proc. Am. Assoc. Cancer Res. 15:#509, 1974.
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26. Flickinger, J.T., Zajac, W. and Kreider, J.W. Replication and Immunosensitivity of Mature B16 Melanoma Cells. Proc. Canad. Fed. Biology Soc. 17:#135, 1974.
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28. Davidson, E.A., Tkacz, J., Bhavanandan, V.P., Banks, J. and Kreider, J.W. Complex Saacharide Production by Cultured Mammalian Cells. 3rd International Symposium on Glyconconjugates, Brighton, England, 1975.
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30. Kreider, J.W. and Bartlett, G.L. Differential Suppression of Tumor Cell-Immune Stimulant Mixtures in Various Sites. Proc. Am. Assoc. Cancer Res. 17:#445, 1976.

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33. DeFreitas, E., Kreider, J.W. and Bartlett, G.L. Immunologic Rejection of Murine Moloney Sarcoma is Unaffected by an Inhibitor of Macrophage Cytotoxicity. Fed. Proc. 36:#5046, 1977.
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35. Purnell, D.M., Bartlett, G.L., Kreider, J.W. and Biro, T.G. Synergistic Effects of Corynebacterium Parvum (CP) of Bordetella Pertussis (BP) Combined with Cyclophosphamide (CY) in the Treatment of Murine Mammary Adenocarcinoma (CAD₂). Fed. Proc. 36:#5152, 1977.
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47. Kreider, J.W. Neoplastic Progression in Shope Rabbit Papilloma. Cold Spring Harbor Conferences on Cell Proliferation "Viruses in Naturally Occurring Cancers", Cold Spring Harbor, N.Y.
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53. Eizuru, Y., Hyman, R., Kreider, J.W. and Rapp, F. Map Positions on Herpes Simplex Virus (HSV) in An HSV-1-Transformed Hamster Cell Line. Cold Spring Harbor Conference on Herpesvirus, 1982.
54. Howell, L.E., Kreider, J.W. and Bartlett, G.L. T Cell Requirement for C. Parvum Destruction of Metastases. Fed. Proc. 42:#5280, 1983.
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Personal

Born: March 24, 1937, Philadelphia, Pennsylvania

Married: June, 1963 to Kathleen Ann

Children: Two, Eric and Ted

1955-1959 A.B. in Biology cum laude
La Salle College, Philadelphia, Pennsylvania
Alpha Epsilon Delta

1959-1963 M.D., University of Pennsylvania School of Medicine
Research Trainee in Department of Pathology

1963-1964 Internship in Pathology
Yale University Medical School, New Haven, Connecticut

1964-1967 Post-doctoral Fellow, Department of Pathology
University of Pennsylvania
Affiliate Resident, Philadelphia General Hospital

Appointments

1967-1968 Instructor, Department of Pathology
University of Pennsylvania

1968-1971 Assistant Professor, Department of Pathology
College of Medicine, Pennsylvania State University

1971-1978 Associate Professor, Department of Pathology
College of Medicine, Pennsylvania State University

1973-present Joint Appointment, Department of Microbiology
College of Medicine, Pennsylvania State University

Appointments (cont'd)

1978-present	Professor, Departments of Pathology and Microbiology, College of Medicine, Pennsylvania State University
1968-1972	Lecturer, Graduate Faculty, Pennsylvania State University
1972-1975	Associate Member, Graduate Faculty, Pennsylvania State University
1975-present	Senior Member, Graduate Faculty, Pennsylvania State University
1975-present	Chief, Division of Experimental Pathology, Department of Pathology
1976-1986	Member and Program Director, Specialized Cancer Center, Pennsylvania State University
1987-present	Member, Cell and Molecular Biology Program, Pennsylvania State University

Scientific Society Memberships

**American Association Advancement of Sciences
Tissue Culture Association
Philadelphia Pathological Society
American Society of Microbiology
Allegheny Branch, American Society of Microbiology
American Association for Cancer Research
American Society for Experimental Pathology
Wildlife Disease Association
American Association of Pathologists and Bacteriologists
American Association of Immunologists
Wainwright Tumor Clinic Association of Pennsylvania
American Society for Preventive Oncology
International Society for Antiviral Research**

License

M.D. 029125 Commonwealth of Pennsylvania

Community Service

1964-1978	Deputy Game Protector, Pennsylvania Game Commission
1969	Lay Advisory Committee, Lower Dauphin School District
1987	Judge, The Harrisburg Academy Science Fair

Awards

- 1963** **Borden Undergraduate Medical Research Award**
- 1963** **Meritorious Medical Research Award, American Society of Clinical Pathology**
- 1969-1973** **Research Career Development Award, U.S.P.H.S.**
- 1984** **Wildlife Conservationist Award, Pennsylvania Game Commission**
- 1980,1981,1982,
1983,1984,1985,
1986,1987,1989,
1990,1992** **Teaching Excellence Awards, Presented by Second Year
Medical Students**
- 1988** **Elected to membership, Alpha Omega Alpha, National Medical Honorary
Fraternity**
- 1987-1988** **Sabbatical Leave, The Pennsylvania State University**
- 1990** **University Faculty Scholar Medal for Outstanding Achievement in Health and
Life Sciences, The Pennsylvania State University**

University Committee Memberships

- 1967-1968** **Faculty Advisor, University of Pennsylvania**
- 1969-present** **Faculty Advisor, The Pennsylvania State University**
- 1969-1970** **Medical Selection Committee (Admissions)**
- 1969-1970** **Ad hoc Committee on Student Problem-Solving Projects**
- 1969-1971** **Ad hoc Committee on Individualized Instruction**
- 1969-1971** **Advisor, Student Newspaper**
- 1970-1978** **Chairman, Medical Education Subcommittee, Pennsylvania Division, American
Cancer Society**
- 1970-1971** **Founding President, Faculty Organization, College of Medicine**
- Faculty Representative on Executive Committee**
- Ad hoc Committee on Senate Reorganization**
- Ad hoc Committee on Environmental Relations**
- 1971-1979** **Cancer Committee, Milton S. Hershey Medical Center Hospital**

University Committee Memberships (cont'd)

1971-1972	Curriculum Committee (Planning of "New" Curriculum)
1972-1974	Planning Committee for Cancer Center at Hershey (Planning of Community-Oriented "Outreach" Program)
1973	Chairman, Nominating Committee, Faculty Organization
1973-1979	Founding Chairman, American Cancer Society Institutional Research Grant Committee
1975	Research Initiation Grant Review Committee
1975-present	Chair, Department of Pathology Promotion and Tenure Committee
1975-present	University Hearing Board, Faculty Alternate
1976-1978	Chemical Safety Committee
1979	Basic Science Program Coordinator, Specialized Cancer Research Center
1979	Ad hoc Discrimination Review Committee
1987	Task Force for Planning Cancer Center
1988-present	Member, Hinkle Society
1989	Research Animal Utilization Group
1989	Library Advisory Committee
1989	Member, Rheumatology Endowed Chair Search Committee
1989	Promotion and Tenure Review Committees, Department of Obstetrics/Gynecology, Department of Comparative Medicine
1989-present	Chairman, Experimental Pathology Faculty Search Committee
1990	Faculty Organization Nominating Committee
1990	Promotion and Tenure Review Committee, George T. Harrell Medical Library
1990	Promotion and Tenure Review Committee, Department of Comparative Medicine
1990-1995	AOA Nominating Committee, Chairman
1991	American Cancer Society - Institutional Research Grant Committee
1991	Hershey Biotechnology Park Planning Committee

University Committee Memberships (cont'd)

1991-present **Member, Biological Chemistry Chair Search Committee**

1993-present **Member, Cancer Center Task Force**

Extra-Mural Consultantships Peer Review Activities:

1964-present **Regular Reviewer for Journals: Cancer Research, Journal of the National Cancer Institute, Journal of Immunology, Science**

Ad hoc Grant Reviews: American Cancer Society, Leukemia Society, National Science Foundation

1970 **N.I.H. Division of Research Grants, Arthritis and Metabolic Diseases Program-Project, ad hoc committee (site visit)**

1974 **National Cancer Institute Cancer Center Review, ad hoc committee (site visit)**

1975 **Biology and Immunology Segment, Carcinogenesis Program, DCCP, NCI, NIH, ad hoc committee (site visit)**

1976 **Cancer Special Program Advisory Committee, NCI, NIH, ad hoc committee (site visit)**

1977 **Sinclair Swine Melanoma External Advisory Immunology Task Force, University of Missouri**

1977-1980 **Veterans Administration Merit Review Board for Immunology ("study section" for review of nationwide VA research)**

1978 **Cancer Special Program Advisory Committee, NCI, NIH, ad hoc study section (site visit)**

1979 **Environmental Protection Agency, (U.S.), establishment of research priorities**

1979, 1980 **Pathology B Study Section, NIH, ad hoc reviewer**

1980 **Chairman, Special Study Section, NIH**

1980-1984 **Pathology B Study Section, NIH, member**

1981-1989 **Editorial Board, Cancer Metastasis Reviews**

1984 **NIH, National Institute on Drug Abuse Special Study Section**

1984-1988 **Study Section for Institutional Research Grants, National Office, American Cancer Society**

1985 **Special Study Section, DRG, NIH**

1986 Metabolic Pathology Study Section, DRG, NIH
 Peer Review Activities (cont'd)
 1986 Special Study Section (Chemical Pathology), DRG, NIH
 1986 Special Study Section (Experimental Immunology), DRG, NIH
 1986 Special Reviewer, Conference Grant, DRG, NIH
 1986-1987 Member, NCI Outstanding Investigator Award Committee, DRG, NIH
 1988 Member, Ad Hoc Technical Review Group for Contract Proposals, NCI, NIH
 1988 Chair, Special Study Section, DRG, NIH
 1990 Member, NIAID, NIH Antiviral Testing Group, Contract Reviews
 1990 Reviewer, Viral Contracts Review, NIAID, NIH, Antiviral Testing Group
 1990 Reviewer, Special Study Section (RFA), DRG, NIH
 1990,1991 Reviewer, Ciba-Geigy Scholars in Biomedical Research, Hershey Medical Center
 1991 Reviewer, Special Study Section (RFA), NIAID, NIH
 1992 Reviewer, Special Study Section (RFA), NCI, NIH
 1992 Chairperson, Special Study Section (Experimental Virology), DRG, NIH
 1992 Chair, Special Study Section, NCI, NIH
 1993 Special Review, Special Study Section, NCI Outstanding Investigator Award Committee, DRG, NIH
 1993 Reviewer, ASHA Research Fund Program
 1993 Special Reviewer, NCI Conference Call
 1994 Reviewer, Study Section, NIH
 1994 Reviewer, ASHA Research Fund Program

 American Cancer Society:
 1970 Member-At-Large, Professional Education Committee, Pennsylvania Division, American Cancer Society
 1970-1975 Chairman and Founder, American Cancer Society Institutional Research Grant, Hershey Medical Center
 1971-1974 Vice-Chairman, Professional Education Committee, Pennsylvania Division, American Cancer Society
 1973-1976 Member, Board of Directors, American Cancer Society, Dauphin County Unit

1973-1976	Member, Professional Education Committee, Dauphin County Unit, American Cancer Society
1974-1975	Chairman, Professional Education Committee, Member, Executive Committee, Budget & Finance Committee Pennsylvania Division, American Cancer Society
1991-present	Member, American Cancer Society Institutional Research Grant Committee, Hershey Medical Center
Miscellaneous Consultancies:	
1964-present	Pennsylvania Game Commission, Consultant and Lecturer on Forensic Pathology and Wildlife Diseases
1966	Department of Public Health Commonwealth of Pennsylvania (Inspection of Clinical Laboratories)
1973-present	Industrial Consultant: Bellco Glass Co., Vineland, N.J.
1974-1977	Tissue Culture Association, Sera and Contamination Committee
1975	Nominations Committee, American Society of Microbiology, Allegheny Branch
1976	Membership Committee, American Society of Microbiology, Allegheny Branch
1985	Genital Papillomavirus Program, Pennsylvania Hospital, Philadelphia, PA
1986	Dept. of Public Health, Commonwealth of Pennsylvania Consultant on potential cancer risks of abandoning Blue Shield reimbursements for circumcisions
1987-present	Blue Cross/Blue Shield for State of Pennsylvania Consultant for evaluation of cancer risks and educational programs to replace circumcision reimbursements
1987-present	Industrial consultant: Upjohn Co., Triton Biologicals, Syntex Inc., Exovir Inc., Bristol-Myers Squibb, Oclassen, Cetus, Genentech, Ciba-Geigy, ISIS Pharm.
1987	Bethesda Research Laboratories, Rockville, MD.
1988	Scientific Advisor in Clinical Research, Janssen Research Council, Janssen Pharmaceutica, Piscataway, NJ.
1989	Scientific Consultant, Abbott Laboratories, North Chicago, IL
1989-1990	Course Consultant, Osler Institute
1989	Scientific Consultant, Merck, Sharp, and Dohme, West Point, PA.
1991	Scientific Consultant, Sterling Drug Company, Albany, NY
1991	Scientific Consultant, Burroughs Wellcome, Research Triangle Park, NC
1991	Scientific Consultant, Connaught Laboratories, Swiftwater, PA

1991 **Scientific Consultant, Matrix Pharmaceuticals, Menlo Park, CA**

1991 **Scientific Consultant, International Diagnostics, Ft. Lauderdale, FL**

1992 **Wyeth-Ayerst, Radnor, PA**

1993 **Merck, Inc., Rahway, NJ**

Invention Disclosures Filed:

- 1985 PSU Disclosure No. 85-709 "Nude Mouse/Human Tissue Bioassay for Agents Inhibiting Human Pathogenic Viruses"
- 1985 PSU Disclosure No. 85-711 "Production of Infectious Virions and Virus Antigens in Human Tissue Grafts to Athymic/Nude Mice"
- 1990 PSU Disclosure No. 90-1009 "Production of Transgenic Rabbits Bearing Cottontail Rabbit Papillomavirus and/or EJras"
- 1990 PSU Disclosure No. 90-975: "Neutralizing Antibodies to Human Papillomavirus Type 11 (HPV-11)"
- 1992 PSU Disclosure No. 92-1177 "In-Vitro Test for Anti-Papillomavirus Drugs"
- 1993 PSU Disclosure No. 93-1204 "Transgenic Rabbit Model for Detecting Mutagen"
- 1993 PSU Disclosure No. 93-1225 "Ribozymes"
- 1994 PSU Disclosure No. 94-1340 "Chimpanzee Model of Human Papillomavirus Infection"
- 1994 PSU Disclosure No. 94-1342 "Artificial Human Vagina for Testing Topical Microbicides"

Patent Applications

- 1991 U.S. Patent Application No. 07/918,302: "High Efficiency Induction of Recombinant DNA Transformation of Mammalian Skin"

Patents

- 1989 U.S. Patent No. 4,814,268: "Methods for Propagating Fastidious Human Viruses and For Producing Purified Suspensions Thereof"
- 1991 U.S. Patent No. 5,071,757: "Methods for Propagating Fastidious Human Viruses and for Producing Purified Suspensions Thereof"

Record of Research Trainees

Former Predoctoral Trainees

Murray Rosenthal, B.S., M.S., D.O.
Psychiatrist, Private Practice
Miami Beach, Florida

Cinda M. Boyer, B.S., Ph.D.
Assistant Medical Research Professor
Department of Medicine
Duke University Medical Center
Durham, NC
1975-1980

Michael G. Angell, B.A., Ph.D.
Postdoctoral Fellow
The University of Michigan
1987-1993

Elaine C. DeFreitas, B.S., M.S., Ph.D.
Associate Professor
The Wistar Institute
Philadelphia, PA
1974-1978

Xuwen Peng, D.V.M., Ph.D.
Postdoctoral Fellow
The Milton S. Hershey Medical Center
The Pennsylvania State University
Hershey, PA
1989-1993

Former Postdoctoral Trainees

Keiji Iizuka, M.D.
Department of Otorhinolaryngology
Akita University School of Medicine
Akita City, Japan
1981-1983

Robert O. Olson, B.S., M.S., Ph.D.
820 Verden Avenue
Hummelstown, PA 17036
1988-1991

Carole B. Christian, B.S., M.S., Ph.D.
Department of Pediatrics
The Milton S. Hershey Medical Center
1989-1992

Reinhard Höpfl, M.D.
Department of Dermatology and Venereology
University of Innsbruck
Innsbruck, Austria
1991-1992

Jeffrey D. Wisotzkey, Ph.D.
Postdoctoral Fellow
Department of Pathology
1990-Present

Neil D. Christensen, B.Sc., M.Sc., Ph.D.
Assistant Professor
Department of Pathology
The Milton S. Hershey Medical Center
1984-1990

Du Chungun, M.D.
Department of Microbiology and Immunology
The Milton S. Hershey Medical Center
1989-1991

Masafumi Okabayashi, M.D.
Department of Preventive Medicine
Osaka University, Osaka, Japan
1989-1992

Kurt Helm, M.D.
Postdoctoral Fellow
Dept. Obstet. Gynecol. (Frauenklinik)
University Hospital Innsbruck
Anichstrasse 35
A-6020 Innsbruck, Austria

Yoshitaka Hagari, M.D., Ph.D.
Postdoctoral Fellow
Department of Dermatology
Tottori University Faculty of Medicine
36-1 Nishi-machi, Yonago 683,
Japan

Present Postdoctoral Trainees

Xuwen Peng, D.V.M., Ph.D.
Postdoctoral Fellow
Department of Pathology
1993-Present

Collaborative/Training Experiences in my Laboratory for Clinicians and Residents

Mary Simmonds, M.D., Division of Oncology
Ernest K. Manders, M.D., Division of Plastic Surgery
James Marks, M.D., Division of Dermatology
Koen DeGeest, M.D., Gynecology Resident
Thomas Rosvanis, M.D., Urology Resident
Louis Martin, M.D., General Surgery
Mark Jarowenko, M.D., Urology
Harold Yang, M.D., Transplant Surgery
Gordon Kauffman, M.D., General Surgery
Natasa Zec, M.D., Pathology Resident
Barbara Miller, M.D., Pediatric Oncology
Peter Furness, M.D., Urology Resident

Ph.D. Committee Service

For over 25 years, I have served on about 2-3 thesis committees each year, including students in Microbiology, Cell and Molecular Biology, Biochemistry, Pharmacology, Comparative Medicine, and Genetics.

Teaching Responsibilities

For about 25 years, my teaching has included the following:

1. I have been Course Coordinator for the "General Pathology" section of the second-year medical student Pathology course. I have taught, at various times, all or part of the sections on Inflammation, Wound Healing, Regeneration, Neoplasia, and Autoimmunity.
2. In the "Systemic Pathology" portion of the course, I have taught portions of GI disease, liver disease, bone, muscle, and joint disease, and skin disease.
3. I have taught the "Obesity" lecture as part of the Endocrine section, in the Medicine Course.
4. I have taught about one-third of the Immunology course for second-year medical students, until about 5 years ago.
5. Initiated and organized "Molecular Biology for Pathology Residents" course.
6. I have founded and taught many topics in a graduate level course in the "Biology of Neoplasia."
7. My lectures have been well received, with evaluations in the highest categories and many awards from the medical students.

Recent Extramural Lectureships

<u>Date</u>	<u>Location</u>	<u>Title of Seminar</u>
8/6/85	Dr. Peter Howley's Group NCI, NIH	"In Vivo Induction of Condylomas in Athymic Mice"
9/16-17/85	Upjohn Corp., Brook Lodge, Kalamazoo, Michigan	"Is there a host response to metastasis?"
11/22-26/85	American Cancer Society Papillomavirus Conference Key Biscayne, Florida	"In Vivo Induction of Condylomata in Athymic Mice?"
1/28/86	State University of NY Stony Brook, NY	"In Vivo Induction of Condylomata in Athymic Mice"
2/3/86-2/7/86	UCLA Symposium Molecular Biology Park City, Utah	"In Vivo Induction of Condylomata in Athymic Mice"
2/18-19/86	NCI Conference on Papilloma- viruses and Cancer, NIH	"In Vivo Induction of Condylomata in Athymic Mice"
3/23-25/86	American Cancer Society Science Writers Conference Daytona Beach, Florida	"In Vivo Induction of Condylomata in Athymic Mice"
4/2/86	Millersburg University Millersburg, PA	"The Biology of Cancer in Man"
4/15/86	Department of Pathology Georgetown University Georgetown, MD	"In Vivo Induction of Condylomata Cancer"
5/12/86	Division of Cancer Biology NCI, NIH	"In Vivo Induction of Condylomata in Athymic Mice"
5/14/86	Department of Pathology University of Massachusetts Worcester, MA	"In Vivo Induction of Condylomata in Athymic Mice"
5/21/86	Department of Pathology University of Rochester Rochester, NY	"In Vivo Induction of Condylomata in Athymic Mice"

Recent Extramural Lectureships (cont'd)

6/19/86	Radio Interview WCAU Philadelphia	
7/28/86	German Cancer Research Center Heidelberg, West Germany	"Transformation of Human Tissues with Human Papillomaviruses"
8/4/86	Radio Interview WCAM Harrisburg	
9/4/86	Papillomavirus Conference Cold Spring Harbor, NY	"Tissue-specific Expression of Human Papillomavirus Type II"
2/2/87	Thirld Wallace Rowe Symposium in Animal Virology	"Condylomatous Transformation of Human Tissues <u>In Vivo</u> with Human Papillomavirus Type 11"
3/26/87	International Symposium on Herpes and Papillomaviruses Milano, Italy	"Morphological Transformation <u>In Vivo</u> of the Human Uterine Cervix by HPV"
4/7/87	Department of Pathology School of Medicine, University Nebraska, Omaha, Nebraska	"Model System for Papillomavirus Transformation of Human Tissues"
5/29/87	Department of Immunology and Infectious Diseases John Hopkins University School of Medicine Baltimore, MD	"Morphological Transformation of Human Tissues and HPV-11 Repli- cation in Athymic Mice"
6/17/87	Sixth International Pap- illomavirus Workshop, George- town University School of Medicine, Washington, D.C.	"Condylomatous Transformation by HPV-11 of Cultured Human Foreskin Keratinocytes Transplanted to Athymic Mice"
8/28/87	Obstetrics and Gynecology Update Conference Annapolis, Maryland	"Human Papilloma Virus Infection and Neoplastic Changes in the Female Genital Tract"
10/3/87	International Titisee Conference on Papillomavirus in Human Genital Cancer: Causative Role and Practical Consequences Titisee, West Germany	"Transplantation of HPV-Infected Human Cells into the Nude Mouse"

Recent Extramural Lectureships (cont'd)

10/22/87	Pennsylvania Hospital Philadelphia, PA	OB/GYN Grand Rounds: "The Future of Human Papillomavirus Treatment" Pathology Conference: "Xenotrans- plants of Human Papillomavirus-Infected Tissues"
10/22/87	Philadelphia Colposcopy Annual Meeting	Keynote Lectureship
3/21/88	American Cancer Society Science Writers' Seminar Daytona Beach, Florida	"Papillomaviruses and Cervical Cancer"
4/5/88	Department of Microbiology/ Immunology Northeastern Ohio University Rootstown, Ohio	"Condylomatous Transformation of Human Tissue with Human Papillomavirus"
5/4/88	Centre County Unit American Cancer Society State College, PA	Keynote Speaker "The Future Offers Hope"
5/16-20/88	Seventh International Papillomavirus Workshop Sophia Antipolis, France	"Beta-Estradiol Stimulation of the Growth of Experimental Human Condylomas Induced with Human Papillomavirus Type 11"
11/9/88	Cancer Support Group, Villa Teresa Nursing Home, Harrisburg, PA	Keynote Speaker "The Future Offers Hope"
3/11-3/18/89	Eighth International Papilloma- virus Workshop, UCLA Symposia on Molecular and Cellular Biology, Taos, New Mexico	Plenary Lecture: "Host Factors Regulating Condylomatous Transformation by HPV-11"
4/25/89 5/2/89	Continuing Education Program, The Milton S. Hershey Medical Center, Hershey, PA	Invited Speaker, "Oncology Career Days"
5/8-10/89	Collaborative Antiviral Testing Group (CATG) of the Microbiology and Infectious Diseases Program of NIAID, NIH, Bethesda, MD	"A Papillomavirus Animal Model for Evaluation of Experimental Therapies"

Recent Extramural Lectureships (cont'd)

6/14-6/17/89	2nd Annual Meeting of the Association of Medical Laboratory Immunologists, Albany, New York	Plenary Lecture: "Immunological Aspects of Papillomaviruses"
6/28/89	Penn State University Students	"Penalties of Love:
9/22/89	Osler Institute Pathology Boards Review Course, Chicago, Illinois	Faculty Lecturer: "General Review of Neoplasia"
10/16/89	Abbott Laboratories, North Chicago, Illinois	Invited Speaker: "Experimental Infection of Human Tissue with Human Papilloma Virus
10/21/89	American Society for Colposcopy and Cervical Pathology, Human Papillomavirus Infections - A Clinical Seminar	Invited Speaker: "Discussion of In Vitro Systems"
11/27/89	Merck, Sharp, and Dohme, Research Laboratories, West Point, PA	Invited Speaker: "Experimental Model of Human Papillomavirus Infection"
12/6/89	Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska	Invited Grand Rounds Speaker: "Warts, Hormones, and Immunity"
12/13/89	Cell and Molecular Biology Program, The Milton S. Hershey Medical Center, Hershey, PA	Invited Speaker: "Warts in Love"
3/31-4/5/90	1990 UCLA Colloquium on "Animal Models of Human Viral Diseases: Relevance to Developmental Therapeutics" Keystone, Colorado	Plenary Lecture: "Treatment of Papillomavirus Infections with Acyclic Nucleotides"
4/18-20/90	American Society of Colposcopy and Cervical Pathology, Biennial Meeting, Washington, DC	Invited Speaker: "Model Systems for Human Papilloma Virus Infections"
5/12-17/90	Papillomavirus Workshop 1990, Heidelberg, Federal Republic of Germany	"Experimental Infection with Human Human Papillomavirus Type 1 of Human Hand and Foot Skin"